PATENT
Attorney Docket No.: UCSD1620-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dillmann et al.	Art Unit:	1633
Application No.:	10/562,524	Examiner:	James Schultz
Filing Date:	September 13, 2006	Confirmation No.:	8043
Title:	USE OF CALCIUM BINDING PROTEINS TO IMPROVE CARDIAC CONTRACTILE FUNCTION		

MAIL STOP AMENDMENT
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

I, Dr. Wolfgang Dillmann, do hereby declare and state that:

1. I hold the position of Professor of Medicine and Division Chief of the Division of Endocrinology and Metabolism, Department of Medicine at the University of California, San Diego.

2. U.S. Patent Application Serial No. 10/562,524, filed September 13, 2006, is a 35 USC §371 National Stage application of PCT Application No. US04/22718 filed June 28, 2004, now abandoned, which claims the benefit under 35 USC § 119(e) of U.S. Application Serial No. 60/484,509, filed July 1, 2003, now abandoned.

3. I am a co-inventor of the invention claimed in the above-identified application.

4. I am familiar with the contents of the above-identified application, and have reviewed the Office Action dated March 4, 2010. I understand that the Examiner has rejected claims 1, 3-14 and 27-29 under 35 U.S.C. §112, first paragraph, on the grounds that the specification allegedly fails to enable one of skill in the art to practice the full scope of the invention as claimed.

5. The Examiner acknowledges that expression of sorcin occurs via direct injection of viral vectors into tissue. However, the Examiner contends that Seidler et al. (*Circ Res.*, 93:132-139 (2003)) show that increased expression of sorcin in cardiac tissue may not be sufficient or even adequate to achieve the claimed function of increasing heart contractility since the reference shows that adenoviral delivered sorcin actually reduced fractional shortening of cardiac muscle cells *in vitro*.

6. As acknowledged by the Examiner, Seidler et al. provide *in vitro* data as opposed to *in vivo* data as provided in the instant application. Regardless of this distinction, attached hereto as Exhibit A is additional data from *in vivo* experiments that have been conducted under my supervision. The data shows that delivery of adeno-associated virus expressing sorcin (AAV-sorcin) to cardiac muscle in the hearts of mice improved cardiomyocyte contractility. Specifically, the data shows that increased sorcin expression improves cardiomyocyte contractility in hearts with heart failure. These results indicate that increased expression of sorcin improves cardiac contractility and therefore presents a viable option for treatment and prevention of diseases which exhibit decreased cardiac output, such as heart failure.

7. This view is shared by other experts in the art. For example, attached hereto as Exhibit B (Frank et al., *Journal of Molecular and Cellular Cardiology*, 38:607-615 (2005)), is a 2005 publication showing both *in vivo* and *in vitro* data of increased cardiac contractility resulting from increased expression of adeno-viral delivered sorcin. Specifically, Exhibit B shows *in vitro* transfection of healthy adult rat cardiomyocytes transfected with adenovirus encoding sorcin, resulting in increased expression of sorcin and improved cardiac contractility (see Exhibit B, entire document). Similarly, Exhibit B shows *in vivo* delivery by direct injection into healthy adult rat heart of adenovirus encoding sorcin, resulting in increased expression of sorcin and improved cardiac contractility (see Exhibit B, entire document).

9. I further declare that all statements made herein of knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 6-30-10

W. D. Illmann

Dr. Wolfgang Dillman, M.D.